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Dated: May 16, 2011
Electronic Signature for Kari Lynn Barnes: /Kari Lynn Barnes/

Docket No.: 292-PDD-99-20-CON-[70P2]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Peter L. Harris et al.

Application No.: 10/603,952 Confirmation No.: 3111

Filed: June 25, 2003 Art Unit: 3738

For: VASCULAR PROSTHESIS Examiner: D. H. Willse

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal of the Final Office Action, mailed September 16, 2010, filed under 37 C.F.R. § 1.191. This brief follows the Notice of Appeal, filed January 18, 2011, and the subsequent Notice of Panel Decision from Pre-Appeal Brief Review, mailed March 16, 2011, which set a deadline of April 16, 2011 for the filing of an Appeal Brief. This brief is filed with a one-month extension of time to extend the deadline for response to May 16, 2011. Accordingly, this brief is timely filed.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Bard Peripheral Vascular, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 21 claims pending in this application.

B. Current Status of Claims

1. Claims canceled: 12-13, 23-26, and 28-32
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 1-11, 14-22, and 27
4. Claims allowed: none
5. Claims rejected: 1-11, 14-22, and 27

C. Claims On Appeal

The claims on appeal are claims 1-11, 14-22, and 27.

IV. STATUS OF AMENDMENTS

Appellant did not file an Amendment After Final Rejection. Accordingly, all amendments submitted to date have been entered and considered on the record.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As described with reference to FIGS. 4 to 8, a vascular prosthetic graft 50 includes a tubular part 52 and an enlargement 54 at one or both ends of the tube 52. "The enlargement 54 has an open end of a generally oval cross-section forming a heel 56 and a toe 58 at opposite ends of the larger diameter of the open end. There is a generally outwardly concave transition 60 between the tube 52 and the heel 56 and between the tube 52 and the toe 58 a firstly convex 62 and a final concave 64 transition." (Instant Specification, p. 6, ¶ [0031].) With respect to FIGS. 9 to 13, a prosthetic graft is illustrated similar to the FIGS. 4 to 8 graft including a narrower portion 70 along the tube 52 prior to commencement of the enlargement in order to increase the velocity of blood flow through the graft connection to the artery. (Specification, p. 7, ¶. [0033].)

As provided in the present description, prior art devices, depicted in FIGS. 1-3, suffer from a tendency for myointimal-hyperplasia after implantation of the prosthetic graft tube 10. (Instant Specification, p. 5, ¶ [0028].) For example, the Miller cuff, aimed at reducing such problems, creates a vortex to increase shear stress. (Specification, p. 6, ¶¶ [0029]-[0030].) However, at opposite sides of the cuff, low shear stress regions 42, 44 develop where accumulation of deposits can form, resulting in intimal hyperplasia. Furthermore, where flow separates at the arterial wall opposite the cuff, a low shear stress region 46 also develops where intimal hyperplasia is possible." (Specification, p. 6, ¶[0030].) The described configuration, as claimed below, overcomes the deficiencies identified in the prior art by including an enlargement which produces blood flow characteristics therein that result in an increase in wall shear stress. (Specification, p. 3, ¶ [0011].)

A. Independent Claim 1 with Embodiments from Claims Depending Therefrom

This invention relates in one aspect to a vascular prosthesis (specification, p. 3, ¶ [0009], FIGS. 4-13), including a generally tubular portion (specification, p. 6, ¶ [0031], ll. 2-3) and an end

formation configured for surgical connection to an opening formed in a blood vessel (specification, p. 7, ¶ [0032], ll. 6-11), the tubular portion including a generally uniform surface and a first diameter that tapers to a smaller second diameter adjacent the end formation (specification, p. 7, ¶ [0033], ll. 3-5, FIGS. 9-13), the end formation defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening (specification, p. 6, ¶ [0031], ll. 4-6), the opening having a non-circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the tubular portion at the first diameter (specification, p. 6 ¶ [0031], ll. 4-8).

The enlarged chamber of the vascular prosthesis, as claimed in dependent claim 2, may include a first diameter parallel to an axis of the tubular portion and a second diameter transverse to the axis of the tubular portion (specification, p. 6, ¶ [0032], FIGS. 4-13), wherein the enlarged chamber first diameter is longer than the enlarged chamber second diameter (specification, p. 6, ¶ [0031]), the enlarged chamber first diameter corresponds to a heel and a toe of the end formation (specification, p. 6, ¶ [0031]), wherein a transition between the tubular portion and the toe is outwardly initially convex before a final concave portion (specification, p. 6, ¶ [0031], ll. 6-8). Further, as claimed in dependent claims 4-5, respectively, the transition between the tubular portion and the heel is generally outwardly concave, (specification, p. 6, ¶ [0031], ll. 6-7), and the portions of the end formation corresponding to opposing ends of the enlarged chamber second diameter are generally outwardly convex (specification, p. 6, ¶ [0031], ll. 8-9). As recited by dependent claim 6, the enlarged chamber first diameter is between approximately 14 and 36 mm and the enlarged chamber second diameter is no greater than approximately 14 mm. (Specification, p. 7, ¶ [0032], ll. 9-11.)

The vascular prosthesis, as claimed in dependent claim 3, includes the enlarged chamber configured to promote localized movement of blood having a non-laminar nature with a shear stress inducing relationship to a wall of the blood vessel. (Specification, p. 3, ¶¶ [0011]-[0012].)

Moreover, as provided by dependent claim 7, the prosthesis may include a second end formation. (Specification, p. 6, ¶ [0031], l. 4.) The second end formation may include a second enlarged chamber comprising a first diameter parallel to an axis of the tubular portion and a second

diameter transverse to the axis of the tubular portion, wherein the second enlarged chamber first diameter is longer than the second enlarged chamber second diameter, the second enlarged chamber first diameter corresponding to a heel and toe of the second end formation, wherein a transition between the tubular portion and the toe is outwardly initially convex before a final concave portion, as recited by dependent claim 8. (Specification, FIG. 14, submitted June 8, 2009.) As generally recited by dependent claims 9-10, respectively, the features of the second enlarged chamber may be similar to that of the first chamber, including a transition between the tubular portion and the heel of the second enlarged chamber is generally outwardly concave (specification, p. 6, ¶ [0031], ll. 6-7), and portions of the end formation corresponding to opposing ends of the second diameter of the second enlarged chamber are generally outwardly convex (specification, p. 6, ¶ [0031], ll. 8-9). The vascular prosthesis, as recited by dependent claim 8, further comprises a decreased diameter portion adjacent the second end formation. (Specification, p. 7, ¶ [0033], ll. 3-5, FIGS. 9-13.)

As recited by dependent claims 14 and 16, the tubular portion, end formation, and/or second end formation of the vascular prosthesis are comprised of a material other than autologous vascular tissue. (Specification, p. 3, ¶ [0010].) Specifically, as recited by dependent claims 15 and 17, the tubular portion, end formation, and/or second end formation may be of a polytetrafluoroethylene material. (Specification, p. 3, ¶ [0010].)

B. Independent Claim 18 with Embodiments from Claims Depending Therefrom

This invention relates in one aspect to a vascular prosthesis (specification, p. 3, ¶ [0009], FIGS. 4-13), including a tube (specification, p. 6, ¶ [0031], ll. 2-3) and an enlargement positioned at a distal end of the tube (specification, p. 6, ¶ [0031], ll. 4-6), the tube comprising a first diameter portion extending along a majority of the length of the tube and a second diameter portion positioned adjacent the enlargement (specification, p. 6, ¶¶ [0031]-[0032]), the first diameter portion having a diameter greater than a diameter of the second diameter portion (specification, p. 7, ¶ [0033]), the enlargement defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening (specification, p. 6, ¶ [0031]), the opening having a non-

circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion (specification, p. 6, ¶ [0031], FIGS. 4-13).

The vascular prosthesis open end perimeter may further have a generally oval shape, as recited by dependent claim 19. (Specification, p. 6, ¶ [0031].) The tube and enlargement may also be of a polytetrafluoroethylene material, as recited by dependent claim 20. (Specification, p. 3, ¶ [0010].)

C. Independent Claim 21 with Embodiments from Claims Depending Therefrom

This invention relates in one aspect to a vascular prosthesis (specification, p. 3, ¶ [0009], FIGS. 4-13), including a tube (specification, p. 6, ¶ [0031], ll. 2-3), a first enlargement positioned at a distal end of the tube (specification, p. 6, ¶ [0031], ll. 4-6) and a second enlargement positioned at a proximal end of the tube (specification, p. 6, ¶ [0031], l. 4), the tube comprising a first diameter portion extending along a majority of the length of the tube (specification, p. 6, ¶¶ [0031]-[0032]), a second diameter portion with a diameter less than a diameter of the first diameter portion positioned adjacent the first enlargement (specification, p. 7, ¶ [0033]) and a third diameter portion with a diameter less than a diameter of the first diameter portion positioned adjacent the second enlargement (specification, pp. 6-7, ¶ [0031], [0033]), at least one of the first and second enlargements defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening (specification, p. 6, ¶ [0031]), the opening having a non-circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion (specification, p. 6, ¶ [0031], FIGS. 4-13). As recited by dependent claim 22, the tube, first enlargement, and second enlargement may be made of a polytetrafluoroethylene material. (Specification, p. 3, ¶ [0010].)

D. Independent Claim 27

This invention relates in one aspect to a vascular prosthesis (specification, p. 3, ¶ [0009], FIGS. 4-13), including a tube defining a central axis (specification, p. 6, ¶ [0031], ll. 2-3; ¶ [0032], ll. 1-2), the tube having a first portion with a constant inner dimension along a first portion of the

central axis (specification, p. 6, ¶¶ [0031]-[0032]) and a second portion with a variable inner dimension along a second portion of the central axis (specification, p. 7, ¶ [0033]), the second portion defining a non-circular opening at an end of the tube (specification, p. 6, ¶ [0031]), the non-circular opening defining a cross-sectional area that is larger than a cross-sectional area of the first portion of the tube (specification, p. 6, ¶ [0031], FIGS. 4-13).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-5, 7-11, 14, 16, 18, 19, and 21 are anticipated under 35 U.S.C. § 102 over Ehrenfeld?

B. Whether claims 6, 15, 17, 20, and 22 are unpatentable under 35 U.S.C. § 103 over Ehrenfeld?

C. Whether claim 27 is unpatentable under 35 U.S.C. 103 over Matterson?

D. Whether claims 1-5, 7, 14, 16, 18, 19, 21, and 27 are anticipated under 35 U.S.C. § 102 over Pintauro?

E. Whether claims 6, 15, 17, 20, and 22 are unpatentable under 35 U.S.C. § 103 over Pintauro?

VII. ARGUMENT

A. Claims 1-5, 7-11, 14, 16, 18, 19, and 21 Rejected under 35 U.S.C. § 102 over Ehrenfeld

The Examiner asserts that US 5,156,619 to Ehrenfeld ("Ehrenfeld") anticipates present claims including a generally uniform surface with a first nominal or minimal inner diameter that tapers to a smaller second nominal or minimal inner diameter adjacent an end formation 23. (Final Office Action, mailed September 16, 2010, ("Office Action") p.2.) Moreover, the Examiner asserts that the crimps of Ehrenfeld impart convexity to portions of the toe region and the generally circular cylindrical geometry likewise defined a convexity. (Office Action, p. 2.) Appellant respectfully disagrees with these assertions at least because the crimps of Ehrenfeld cannot properly be used to support the claimed first diameter portion larger than a second diameter portion. Either, the crimps

support variable diameters, but do not support a uniform surface as claimed, or the crimps constitute a uniform surface that does not taper. As such, Ehrenfeld fails to suggest, for example, the uniform surface tapering between a first and second diameter, of claim 1.

1. Claim 1, and claims 4-5, 14, depending therefrom

Ehrenfeld fails to disclose either the uniform surface or the claimed taper from a first diameter to a smaller second diameter. Instead, Ehrenfeld describes a flanged graft crimped along its length. The varying profile caused by the crimps does not constitute a uniform surface as claimed. Even assuming *arguendo* that the crimps could be considered a uniform surface, that surface does not taper from a first diameter to a smaller second diameter. Instead, the crimped surface has a constant profile along its length.

Ehrenfeld shows and describes a flanged end-to-side vascular graft having an integrally formed flange at one end. (Ehrenfeld, Abstract.) "Graft 11 is formed of a polyester fiber, either knit or woven, compacted and given a series of circular crimps 16 about main body 12 and legs 13 and 14." (Ehrenfeld, col. 2:2-5.) "In order to use graft 11 for an end-to-side anastomoses, graft 11 has been cut along a line 18. This provides a flanged graft 21 as shown in FIG. 2 having a straight portion 22 with an integrally formed flange portion 23." (Ehrenfeld, col. 2:6-9.)

Ehrenfeld fails to show or describe a generally uniform surface, as claimed, since it comprises the crimp along its length. With respect to the purported disclosure of a generally uniform surface, the cited Ehrenfeld passage (col. 1:65 to col. 2:5) describes reinforcing a bifurcated graft through stitches to close space between legs formed during knitting or weaving, and also the presence of circular crimps about the body and legs of the graft. Nowhere is a generally uniform surface shown or described by Ehrenfeld. Indeed, the presence of crimps necessarily means that any tubular portion shown does not include a "generally uniform surface," as recited in independent claim 1.

In response to this argument, the Examiner defines "uniform" as "presenting an unvaried appearance of surface, pattern, or color." (Office Action, p. 4.) Independent claim 1 recites a

"uniform" surface. Accordingly, using the Examiner's definition, the uniform surface "presents an unvaried appearance of surface." The crimps vary the surface, and thus are not uniform, as claimed.

Even assuming *arguendo* that the crimped surface is taken as the uniform surface, Ehrenfeld still fails to identify the taper to a smaller second diameter as claimed. The Examiner asserts that the crimped surface of Ehrenfeld creates the generally uniform surface with an associated diameter. (Office Action, p. 2.) As claimed, the uniform surface has a first diameter. As such, the minimum, maximum, or some intermediate diameter taken to correspond to the crimped surface of Ehrenfeld is the defined diameter for that section. The entire crimped section is associated with that defined diameter, regardless of the location along the crimp, i.e. at the peak or valley. As the entire tube has the same diameter as defined by the "uniform surface," there is no taper. In other words, since the Examiner has taken the crimped surface as the uniform surface, then the taper would have to be of the crimped surface and not caused by the crimp itself. No such feature is shown or suggested by Ehrenfeld. In fact, the Examiner previously admitted that "Ehrenfeld however fails to disclose that the diameter of the tubular portion prior to the end formation has a smaller diameter than the remainder of the tubular portion." (Office Action, March 4, 2005, p. 3.) Instead, Ehrenfeld shows the opposite as two separate tubes expand to the space of a single tube. As such, the diameters of the two adjacent tubes would increase to the diameter of the single enlarged tube.

In view of the above, Appellant submits that the crimps formed in the Ehrenfeld graft cannot fairly be interpreted as a tubular portion including a generally uniform surface that tapers from a first diameter to a smaller second diameter.

2. Claim 2

Ehrenfeld fails to disclose a diameter of the enlarged chamber parallel to an axis of the tubular portion. The perimeter of the asserted enlarged chamber of Ehrenfeld does not include any diameter parallel to the axis of the tubular portion. Instead, the Ehrenfeld asserted chamber is open along any line parallel to the tubular portion. Accordingly, Ehrenfeld fails to disclose the claimed enlarged chamber. Moreover, as shown, the flanged section of the Ehrenfeld graft ends at the

asserted toe section at a valley of the crimp; therefore, the toe section ends in an outwardly convex portion and not the claimed concave portion.

Ehrenfeld FIG. 4 is provided below, left, annotated with lines parallel to the axis of the tubular portion. As previously defined by the Examiner, diameter is "[a] straight line segment passing through the center of a figure, esp. of a circle or a sphere, and terminating at the periphery." (Office Action, dated February 17, 2006, citing Webster's II New Riverside University Dictionary, 1984.) As seen by the annotated figure below, no line terminates in the periphery that is parallel to the tubular portion. Instead, Ehrenfeld includes an open end along the outer extent of any line parallel to the tubular portion. In contrast, annotated FIG. 12 of the present specification is provided below, right, to illustrate an exemplary diameter parallel to the tubular portion that terminates at the periphery of the enlarged chamber.

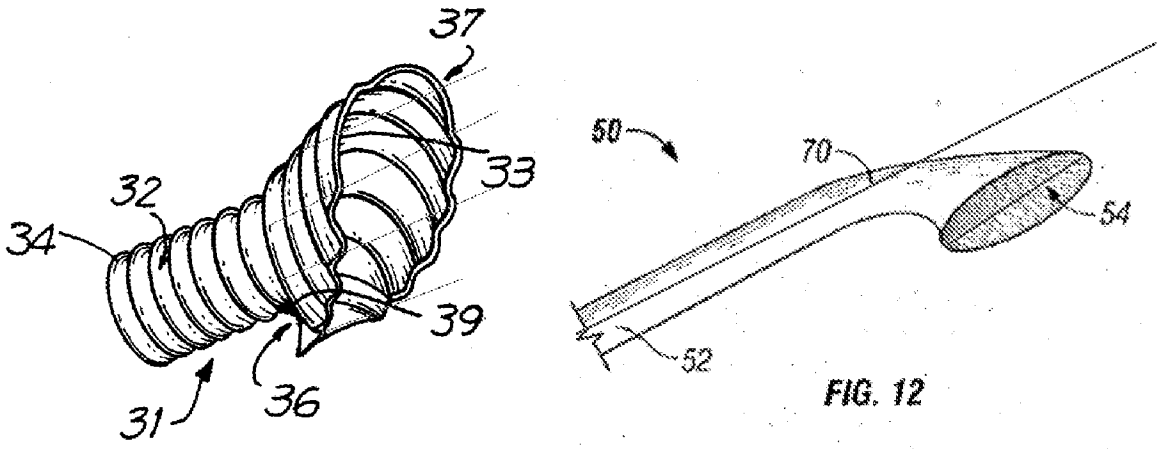


FIG. 12

Moreover, Ehrenfeld fails to disclose the transition between the tubular portion and the toe as outwardly initially convex before a final concave portion. Even assuming the crimps define convexity as proposed by the examiner, as seen in FIG. 5, the toe section terminates in a outwardly convex portion and not the claimed final concave portion.

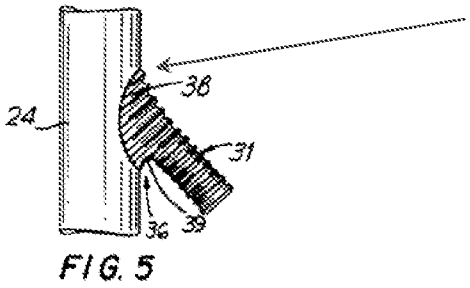
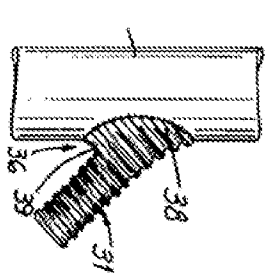


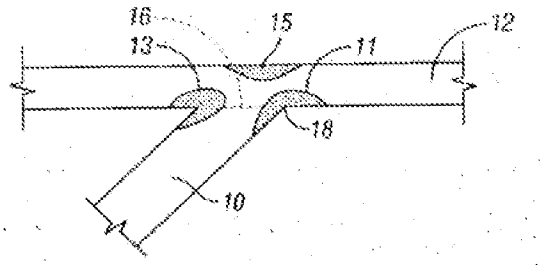
FIG. 5

Accordingly, in view of the above, Ehrenfeld fails to show or describe the generally uniform surface including the first diameter that tapers to a smaller second diameter, as recited by independent claim 1, but also fails to show or describe the orientation of the enlarged chamber including the first diameter and the transition between the tubular portion and the toe.

3. Claim 3

Ehrenfeld fails to disclose a non-laminar nature with a shear stress inducing relationship to a wall of the blood vessel. Ehrenfeld is silent with respect to the laminar nature and shear stress inducing relationship of the transported blood with respect to the wall of the blood vessel. In fact, the Ehrenfeld graft, when attached, as seen in FIG. 5, below left, has a similar profile to the prior art profile identified as FIG. 1 of the present application, below right, noted as lacking the claimed shear stress relationship indicated by number 15. Accordingly, the Examiner has not made a *prima facie* case of anticipation with respect to the recitations of claim 3.





4. Claims 7 and 16

Ehrenfeld does not inherently provide for a second end formation. "Regarding claim 7 and others, [the Examiner asserts that] a second end formation would have been inherent from column 1, lines 5-8." (Office Action, p. 2.) Appellant respectfully disagrees as the cited reference does not require a second flange.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " (MPEP 2112, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).) "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (MPEP 2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).)

Ehrenfeld recites that the "invention relates to synthetic vascular grafts, and more particularly to synthetic vascular grafts having an integrally formed flange on at least one end to facilitate end-to-side anastomoses." (Ehrenfeld, col. 1, ll. 5-8.)

From the recitation above, Ehrenfeld does not make clear that the missing descriptive matter (i.e. a second end formation) is necessarily present in the graft described. Moreover, the recited passage requires only an integrally formed flange on one end of the graft, but does not specifically provide anywhere in the disclosure for a flanged end on the second end. As such, Ehrenfeld does not inherently disclose the claimed second end formation.

5. Claims 8 and 9, 10

Ehrenfeld does not inherently disclose a second end formation as generally described above with respect to claim 7, section VII.A.4. Even assuming that a second end formation is provided by

Ehrenfeld, the specifics of the second flange are not provided. Even assuming further that the same flange is included on both ends of the vascular prosthesis of Ehrenfeld, which is not specifically or inherently provided for by Ehrenfeld, the second end still fails to disclose a formation with an enlarged chamber having a first diameter as claimed, similar to claim 2 discussed above, section VII.A.2. Specifically, Ehrenfeld fails to show or describe a diameter of the asserted end formation parallel to an axis of the tubular portion, since the Ehrenfeld graft is open along the outer end of any line parallel to the tubular portion. Ehrenfeld also fails to show or describe the final concave portion of the transition between the tubular portion and the toe, since the final crimp at the toe of Ehrenfeld is outwardly convex, as discussed above with respect to claim 2, section VII.A.2. Accordingly, Ehrenfeld does not support of *prima facie* case of anticipation with respect to claims 8, 9, and 10.

6. Claim 11

As shown above, sections VII.A.4-5, Ehrenfeld does not inherently provide for a second end formation, nor provide the specifics of any second end formation including an enlarged chamber including a first and second diameter as claimed. Moreover, Ehrenfeld fails to disclose a decreased diameter portion adjacent the second end formation. Similar to the asserted decreased diameter of claim 1, the crimps of Ehrenfeld do not provide a decreased diameter portion as claimed. Accordingly, Ehrenfeld does not support a *prima facie* case of anticipation with respect to claim 11.

7. Claim 18, and claim 19, depending therefrom

Ehrenfeld fails to disclose a first diameter portion extending along a majority of the length of the tube and a second diameter portion positioned adjacent the enlargement, where the first diameter portion has a diameter greater than a diameter of the second diameter portion. Similar to claim 1, presented above, section VII.1.A., the crimps of Ehrenfeld do not provide a separate first and second diameter portion as claimed. Specifically with respect to claim 18, no diameter associated with the crimp of Ehrenfeld would constitute a diameter extending along a majority of the length of the tube. Accordingly, Ehrenfeld fails to disclose multiple variable diameters so that no one diameter extends along a majority of the tube.

In response, the Examiner asserts that "there is nothing in the language that requires the 'first diameter portion' to possess *only one* diameter." (Office Action, p. 4.) Appellant respectfully disagrees since claim 18 recites a "first diameter portion extending along a majority of the length of the tube." Accordingly, a "first diameter" equates a portion of the tube to one diameter. That same "first diameter" of a single diameter extends along a majority of the length of the tube. As such, only one diameter extends along the length of the tube. "Claims are construed with an eye toward giving effect to all terms in the claim." (*Bicon Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006).) An interpretation of "a first diameter portion extending along a majority of the length of the tube" including a variable diameter in effect renders meaningless, or superfluous, the recitation of the diameter extending along a majority of the length of the tube.

Even assuming *arguendo* that one diameter could be associated with the crimped graft, Ehrenfeld fails to show or describe two separate diameter portions where the first diameter portion has a diameter greater than the diameter of the second diameter portion. In order for Ehrenfeld to disclose a "first diameter portion extending along a majority of the length of the tube," the crimped tube of Ehrenfeld would have to be defined by a single diameter, e.g. a maximum diameter at a crimp peak. This diameter would be associated to the entire crimped tube, and therefore, the entire tube of Ehrenfeld outside of the asserted end formation would have the same diameter. Therefore, Ehrenfeld cannot teach both a first diameter portion extending along a majority of the length of the tube, and a second diameter portion, as claimed.

The Examiner further asserts that "Applicant's own pertinent embodiment having the narrowed portion 70 appears to also include a tapering 'first diameter portion extending along a majority of the length of the tube," referring to FIGS. 9, 11, and 13.) (Office Action, p. 4.) Appellant respectfully submits the below annotated FIG. 11 showing a single diameter extending along a majority of the length of the tube, and a tapered portion only over a relatively short section of the tube adjacent the end formation. As shown, the first diameter portion is along a majority of the length of the tube, even without considering the non-represented cut away portion indicated at the left hand side of the figure.

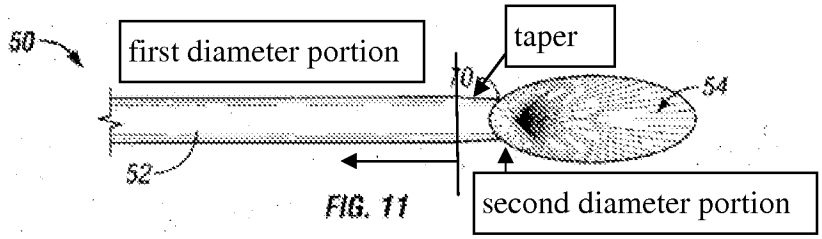


FIG. 11

In view of the above, Ehrenfeld fails to show or describe the features of independent claim 18 including the first diameter portion extending along a majority of the length of the tube and a second diameter portion.

8. Claim 21

Ehrenfeld fails to disclose a first diameter portion extending along a majority of the length of the tube and a second diameter portion positioned adjacent the enlargement, where the first diameter portion has a diameter greater than a diameter of the second diameter portion, as shown above with respect to claim 18, section VII.A.7. Moreover, Ehrenfeld fails to disclose a second enlargement or a third diameter as claimed. Similar to claims 7, 8, and 11 above, sections VII.A.4-6, Ehrenfeld does not inherently disclose a second enlargement or the specific features of any second enlargement. Even if the same Ehrenfeld feature were duplicated at each end, Ehrenfeld still fails to disclose a third diameter portion adjacent the second enlargement similar to the failure to disclose the second diameter portion adjacent the first enlargement. Accordingly, Ehrenfeld does not support of *prima facie* case of anticipation with respect to claim 21.

B. Claims 6, 15, 17, 20, and 22 Rejected under 35 U.S.C. § 103 over Ehrenfeld

1. Claim 6

The Ehrenfeld disclosure of sizes up to 12 mm and typically up to 8 mm does not render obvious the claimed range of 14 to 36 mm. The Office asserts that "[r]egarding claim 6, diameters within the particular ranges would have been obvious from the ranges specified by Ehrenfeld and from the diversity of blood vessel sizes known to the ordinary practitioner." (Office Action, pp. 2-3.) Appellant respectfully disagrees, as Ehrenfeld specifically provides for a range outside of the

claimed range to accomplish end-to-side anastomoses. Given Ehrenfeld's description of the prior art, including the wide usage of vascular grafts, it appears as though a person of skill in the art, e.g. Ehrenfeld, considered the diversity of blood vessels and still chose ranges outside of the presently claimed ranges.

Pursuant to MPEP § 2143.01, IV, the mere statement that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness. Under *KSR*, "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007) *quoting In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Accordingly, Appellant respectfully submits that the claimed diameters are not obvious in view of Ehrenfeld and the diversity of blood vessel sizes known to the ordinary practitioner. The Examiner fails to provide some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness to change the disclosed ranges of under 12 mm to the claimed ranges over 14 mm. As such, Ehrenfeld does not render claim 6 *prima facie* obvious.

2. Claims 15, 17, 20, and 22

Ehrenfeld does not suggest the claimed polytetrafluoroethylene material, instead utilizing a texturized Dacron yarn construction. The Examiner suggests that "PTFE would have been an obvious alternative thread or coating in view of column 1, lines 13-20." (Office Action, p. 3.) The recited reference describes prior art vascular grafts known to Ehrenfeld made of biologically compatible materials including polytetrafluoroethylene (PTFE). However, despite knowledge of the PTFE material, Ehrenfeld still states that "[p]rosthesis 31 illustrated in FIG. 4 is made of 100% texturized Dacron yarn construction." (Ehrenfeld, col. 4:25-26.) As such, the given description of the prior art does not make PTFE an obvious alternative given the clear preference of Ehrenfeld to use the Dacron yarn. Instead of providing for the interchangability of these materials, Ehrenfeld is simply describing different grafts known in the art. In the absence of an articulate rationale to

support the proposed substitution of the PTFE with the described Dacron yarn, the Examiner has not sufficiently established a *prima facie* case of obviousness.

C. Claim 27 Rejected under 35 U.S.C. 103 over Matterson

US 4,530,113 to Matterson ("Matterson") fails to suggest the claimed first portion with a constant inner dimension since the Matterson graft includes pleats along its length. It would not be obvious to remove the pleats of Matterson to provide the claimed constant inner dimension as the pleats prevent the collapse of the graft when implanted and permit a variable axial length. The Matterson graft further fails to provide a second portion with a variable inner dimension along a second portion of the central axis, as the oblique cut at the end of the Matterson graft does not vary the dimensions of the graft. Accordingly, Matterson does not support of *prima facie* case of obviousness of claim 27.

The Office Action alleges that forming the shunt 10 of FIG. 6 without the pleats or corrugations 12 would have been an "obvious step backward" in order to simplify manufacture. The Office Action further alleges that the inner arc lengths and diameters along the ends are "variable by virtue of the oblique cut." (Office Action, p. 3.) Appellant respectfully disagrees.

Matterson shows and describes a graft prostheses woven with cross-weave patterns to prevent unraveling and to increase suture hold strengths. (Matterson, Abstract.) "The graft 10, which is initially woven in a flat tubular configuration as two overlaid, interconnected sheets, is appropriately shaped into its final configuration. The woven tube is placed on a cylindrical mandrel and then crimped." (Matterson, col. 6:46-50.) "To avoid kinking the graft 10 while connecting it to the two openings 42 through the side of a generally straight-line blood vessel, the ends 44 of the graft are cut at an angle oblique to the axis of the graft." (Matterson, col. 7:7-11.)

First, Matterson teaches crimping the graft to provide circumferential pleats or corrugations "that help maintain the graft in its open tubular configuration even as it is bent during surgery to accommodate to anatomical requirements." (Matterson, col. 6:50-54.) Further, the "circumferential corrugations 12 ... expand and contract in accordion or pleated fashion to provide a variable axial

length." (Matterson, col. 3:29-33.) Thus, the alleged obvious step backward, instead of being beneficial as suggested, would render the Matterson graft inoperable for its intended purpose, according to Matterson, as the graft would be prone to closing or bending during surgery.

In response to this argument, the Office Action further alleges that "such variants are advantageous[ly] economical[], in that the crimping step and possibly the heating step . . . are not required." (Office Action, p. 5.) This does not change the requirements set forth in MPEP § 2143(A), however. "The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." (MPEP § 2143(A), emphasis added.) Further, as set forth in MPEP § 2143.01, under *KSR*, "[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Thus, even supposing the manufacturing is advantageously economical, the lack of the crimps provides a graft unsuitable for its intended purpose of providing a bypass to a blood vessel, as the graft would close during surgery and not accommodate the anatomical requirements by providing the desired variable length.

Second, even assuming *arguendo* that the "obvious step backward" did not render the Matterson graft inoperable for its intended purpose, there is no disclosure of a "second portion with a variable inner dimension along a second portion of the central axis," as claimed. As Matterson is simply a tube with an oblique cut end, the inner dimension along the central axis does not change. The oblique cut of the Matterson graft does not change the inner dimension of the graft lumen, and therefore cannot confer to the graft a variable inner dimension along a second portion of the central axis.

In response to this argument, the Office Action further alleges that "[t]he generally elliptical shape created by the oblique cut innately involves a continuum of diameters (i.e., lengths of straight lines through an elliptical center or across circular arcs)." (Office Action, p. 5.) However, the

variable inner diameter recited in claim 27 is "along a second portion of the central axis," where "the central axis," is the same axis as the constant inner dimension of the first portion. The continuum of diameters along the oblique cut relied upon in the rejection is not along the central axis. Since the oblique cut is the asserted second portion and not part of the first portion, there would be no associated inner dimension of the first portion along the oblique cut. Accordingly, Matterson does not show a second portion with a variable inner dimension *along a second portion of the central axis*, as claimed. As such, the inner dimension of the tube along the central axis does not change by the oblique cut at the end of the tube, but is instead defined by the tube itself.

D. Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 Rejected under 35 U.S.C. § 102 over Pintauro

The Examiner asserts that US 5,782,916 to Pintauro et al. ("Pintauro") anticipates select claims of the present application. Pintauro Figure 13 assertedly illustrates an end formation 114 *capable* of connection to a blood vessel opening with a first diameter portion surrounding the valve 124 and tapering to a smaller second diameter portion adjacent the end formation 114, which defines openings having non-circular perimeters. (Office Action, p. 3.) Appellant respectfully disagrees as Pintauro fails to show or describe the separate diameter/inner dimension portions of the tube, as recited generally by the independent claims, or the enlarged chamber.

1. Claim 1, and claims 4, 5, 14, and 16 depending therefrom

Pintauro fails to show or describe a vascular prosthesis, instead providing for a urinary continence device anchored within the bladder. The Pintauro device could not function as a vascular prosthesis as it is designed to stop fluid flow in contradiction to the primary purpose of a vascular device. Similarly, given the design consideration for the anchor to non-surgically secure the device within a bladder, the Pintauro incontinence device is not capable for surgical connection to an opening formed in a blood vessel, as recited by independent claim 1. Pintauro also fails to disclose a first diameter that tapers to a smaller second diameter adjacent an end formation, instead showing the exact opposite configuration with the tubular portion expanding into an anchoring portion.

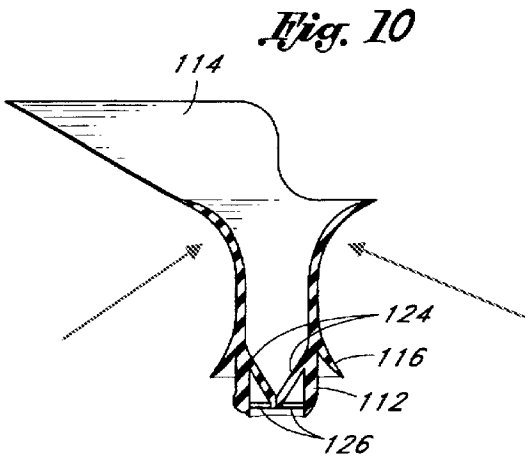
Pintauro shows and describes a prosthetic device for controlling urinary continence. (Pintauro, Abstract.) The valve assembly includes a tubular body 12 and "a first anchor 14. The first anchor preferably conforms to a portion of a base 32 of a bladder 30 as illustrated in FIGS. 4 and 5. The first anchor 14 functions to releasably secure the valve assembly 10 relative to the bladder 30 and the urethra 40." (Pintauro, col. 3:44-48.) The anchor is mechanically biased in the direction of an enlarged configuration to help prevent the valve assembly from being expelled distally from the urethra. (Pintauro, col. 3:60-4:3.) Reinforcing rings 15 and/or 17, fine gauge spring wire, spring bias, or flexible struts may be used to provide adequate anchoring while minimizing the total contact area of the anchor. (Pintauro, col. 4:21-44.) "The valve assembly 10 also includes a valve 24, such as a duckbill valve, which is preferably located within the fluid flow path through tubular body 12 between the proximal end 18 and the distal end 20." (Pintauro, col. 5:7-10.) "FIGS. 12 and 13 illustrate the kinking feature of the tubular body 112 .... As can be seen, during the hypermobility event, the proximal portion of the tubular body 112 kinks or collapses, which helps to maintain continence without having to unduly increase the opening pressure of the valve 124." (Pintauro, col. 7:60-8:2.)

In contradistinction to the assertions made in the Office Action, the Pintauro device is not capable of connection to a blood vessel opening. Instead, the Pintauro device is designed and configured for implantation into the bladder and urethra without direct attachment to tissue. The Pintauro attachment is achieved by the expansion of the anchor 14 through reinforcing rings, spring wires, flexible struts, etc. The Pintauro expansion structures prevents the Pintauro anchor from conforming to a blood vessel and permitting attachment therebetween. Instead, these structures would distort and traumatize a blood vessel if the Pintauro prosthesis were used as a vascular prosthesis as proposed by the Office. Moreover, the rubber used for the Pintauro device would not facilitate suturing to a blood vessel. Instead, the Pintauro device is intended for non-surgical placement to anchor the device within the bladder.

The Pintauro device is similarly not capable for use as a vascular prosthesis. The addition of the valve within the fluid flow path to close the fluid flow for low pressure differentials would stop the flow of blood if used as a vascular prosthesis as proposed. Moreover, the asserted reduced

diameter section of Pintauro is provided by a "kinking feature" of the prosthesis. As is known in the art, kinking and collapse of a vascular prosthesis is not desirable as it obstructs blood flow in the patient, leading to potentially undesirable outcomes. Therefore, even assuming *arguendo* that the valve would be a desirable feature to regulate fluid for a given pressure, the uncontrolled kinking of the prosthesis results in a device unsuitable for vascular applications. Accordingly, Pintauro does not show or describe a prosthesis properly capable of connection to a blood vessel opening to be used as a vascular prosthesis.

With respect to the allegation that Pintauro describes a first diameter portion tapering to a smaller second diameter portion adjacent the end formation, Applicants respectfully submit that Pintauro actually shows and describes precisely the *opposite* configuration, i.e., a first diameter portion tapering to a larger second diameter portion adjacent the end formation. This can clearly be seen in Pintauro FIG. 10 reproduced below, which is annotated with arrows to show the portion adjacent the end formation.



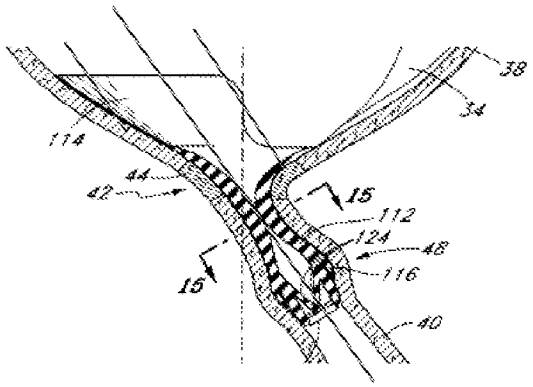
In response, the Examiner states that "Applicant replicates Figure 10 of Pintauro et al. but appears to overlook the configuration of Figure 13 clearly relied upon in the grounds of rejection." (Office Action, p. 5.) However, Appellant respectfully points out that FIGS. 8-15 provide different views of the same embodiment, referred to in Pintauro as the "alternate embodiment." (Pintauro, col. 6, ll. 65-66.) Accordingly, as shown in FIGS. 8, 9, and 10, which are views of the same

embodiment as FIG. 13, Pintauro does not show or describe the features alleged to be disclosed. Accordingly, Pintauro does not show or describe "a first diameter that tapers to a smaller second diameter adjacent an end formation," as recited in independent claim 1.

2. Claim 2

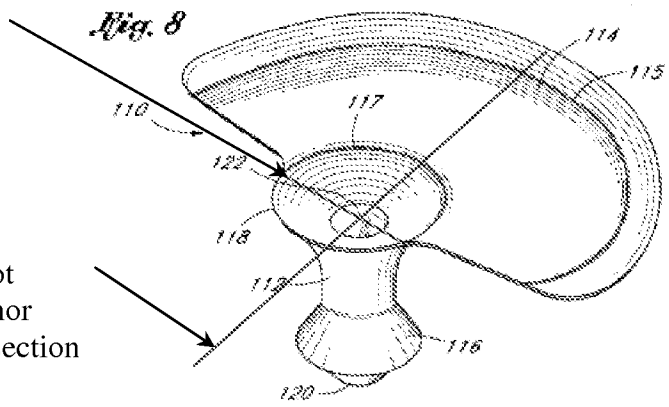
Pintauro fails to disclose a diameter of the enlarged chamber parallel to an axis of the tubular portion. The perimeter of the asserted enlarged chamber of Pintauro does not include any diameter parallel to the axis of the tubular portion. Instead, the Pintauro asserted chamber is open along any line parallel to the tubular portion. Accordingly, Pintauro fails to disclose the claimed enlarged chamber. Moreover, Pintauro does not provide a second diameter transverse to the axis of the tubular portion where the first diameter is longer than the second diameter. The only portion of the Pintauro anchor, asserted enlarged chamber, that provides a boundary for a diameter transverse to the tubular portion axis is generally circular. As such, the diameters associated with the circular anchor are equal.

Pintauro FIG. 13 is provided below, left, annotated with lines parallel to the axis of the tubular portion. As previously defined by the Examiner, diameter is "[a] straight line segment passing through the center of a figure, esp. of a circle or a sphere, and terminating at the periphery." (Office Action, dated February 17, 2006, citing Webster's II New Riverside University Dictionary, 1984.) As seen by the annotated figure below, no line terminates in the periphery that is parallel to the tubular portion. Instead, Pintauro includes an open end along the outer extent of any line parallel to the tubular portion.



Moreover, as seen in Figure 8, annotated below, the only portion of the asserted Pintauro end formation 114 that includes transverse diameters is the circular section 118. As such, the transverse diameters of the circular section would be equal, and not one longer than the other, as claimed.

transverse diameter only available here, as anchor encloses this section

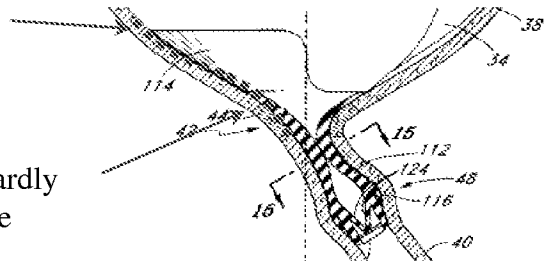


transverse diameter not available here, as anchor does not enclose this section

Finally, Pintauro fails to disclose the transition between the tubular portion and the toe as outwardly initially convex before a final concave portion. As seen in Figures 10-13, the transition from the asserted tubular portion to the toe portion is either constant (FIG. 10) or exactly opposite as claimed, being initially outwardly convex before a final concave portion (FIG. 13). Pintauro Figure 13 is reproduced below annotated with an exaggerated border, in red, representing the curvature of the transition between the asserted tubular portion and the toe. As seen, the transition in initially outwardly concave before a final convex portion. The Examiner even asserts that the *internal* toe surface is concave. (Office Action, p. 3.) However, as claimed, it is the external concavity that is of interest. As such, since the Examiner admits that the internal surface is concave, the external surface would be convex, in contradiction to the claim.

transition outwardly finally convex

transition outwardly initially concave



Accordingly, in view of the above, Pintauro fails to show or describe the claimed recitations of claim 1, including the first and second diameter, and the transition from the tubular portion to the toe.

3. Claim 3

Pintauro fails to disclose a non-laminar nature with a shear stress inducing relationship to a wall of the blood vessel. Since Pintauro is directed toward a bladder implant for assisting in urinary incontinence, there is no reference to the relationship of flow to the wall of a blood vessel. Since the Pintauro device would prevent blood flow, as described above with respect to independent claim 1, section VII.D.1., Pintauro does not provide for a non-laminar nature with a shear stress inducing relationship, as claimed. Even if blood were to flow through the Pintauro device, there is no suggestion that the Pintauro configuration would create a shear stress inducing relationship to the wall of the blood vessel. Accordingly, a *prima facie* case is not supported by the present rejection over Pintauro.

4. Claims 7 and 16

Pintauro does not provide for a second end formation as claimed. The Examiner does not provide any proposed features to constitute the asserted second end formation. As seen in Pintauro FIG. 10, the second end of the tubular portion terminates without change to its profile. Pintauro does provide an intermediate anchor 116 and an internal valve 124, however, these features are not an end formation, as claimed.

5. Claim 18

Pintauro is directed to a device for maintaining urinary continence, the device is inserted in a *nonsurgical* procedure using a cystoscope. (Pintauro, col. 9:8-14.) With respect to the allegation that Pintauro may be used as a vascular prosthesis, Appellant respectfully disagrees. The Pintauro device, as clearly shown in FIGS. 1 and 8, has an anchor 114 that extends only *partially* around the end 18, 118 of the tubular body 12, 112. The Examiner admits that "the 'anchor 14 can extend

circumferentially up to as much as from approximately 270° to 300°' (Pintauro et al.: column 4, lines 10-11)." (Office Action, p. 5.) Appellant respectfully points out that this means that an at least 60° portion is open. Appellant notes that this is more than enough open area to allow a great deal of leakage to occur. Further, the Office Action alleges that "nothing in Applicant's claim 1 and other require the opening to be planer." (Office Action, p. 5.) Even if not required to be planar, independent claims 1, 18, 21, and 27 each recite a "vascular prosthesis." The Pintauro device would not work as such at least because it would leak due to the large portion missing from the anchor. Accordingly, the Pintauro device does it provide for a vascular prosthesis as recited in each of independent claims 18.

Moreover, as discussed above with respect to claim 1, Section VII.D.1, Pintauro does not show or describe a first diameter portion having a diameter greater than a diameter of the second diameter portion. Instead, as seen in FIG. 12, the asserted tube of Pintauro has a constant diameter along its entire length. The only second diameter portion asserted by the Pintauro device, shown in FIG. 13, is the same device as FIG. 12, in a bent configuration to kink the tube and prevent incontinence. "As illustrated in FIG. 13, however, the increased distance between the valve 124 and the proximal end of the tubular body 112 of the alternate embodiment allows the tubular body to kink during a hypermobility event, thereby occluding the lumen of the tubular body, which helps prevent undesired leakage of urine through the valve assembly." (Pintauro, col. 7:53-59.) As such, the tube of Pintauro does not have a first and second diameter portion, but instead has a constant diameter along its length. Even assuming *arguendo* that the kinked configuration creates a second smaller diameter portion, such a configuration becomes unsuitable for a vascular prosthesis, as described above, section VII.D.1.

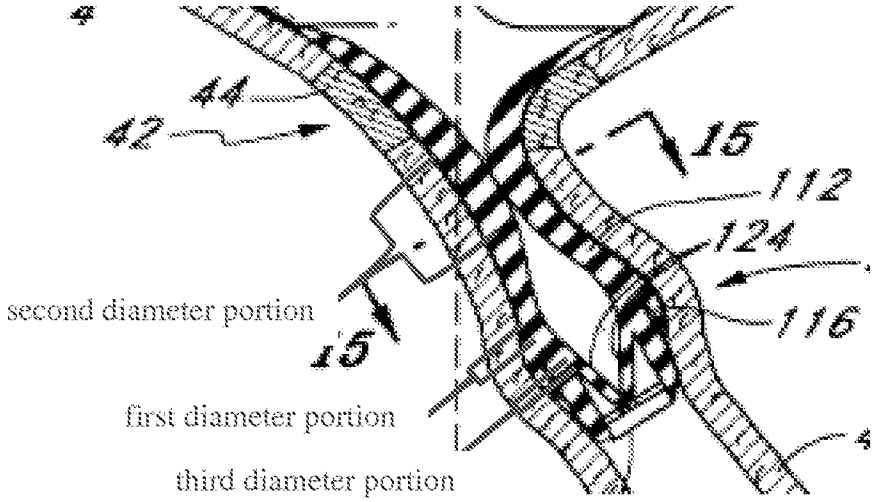
Accordingly, Pintauro fails to anticipate the claimed vascular prosthesis at least because the bladder device of Pintauro is not capable for use as a vascular prosthesis and because it fails to describe the first and second diameter portions, as claimed.

6. Claim 19

Pintauro does not provide for the open end perimeter to have a generally oval shape. Instead the *perimeter* of the open end is an overlay of a two half circles of different radii. As claimed, the enlarged chamber *terminates* at an open end of the prosthesis to define an opening; that open end perimeter having a generally oval shape. The terminal end of the Pintauro device is the anchor 114 that has a perimeter generally circular along an arc of 100° to 180° and then flat to a smaller generally circular section around the remainder of the perimeter. The various circular arcs are not oval shape. The oval opening through the tubular portion, as shown in FIGS. 14-15 are not the claimed opening as they are the cross section of the tubular portion, unrelated to the asserted enlarged chamber, and are not near the terminal end of the enlarged chamber. As such, Pintauro fails to show or describe the claimed open end perimeter.

7. Claim 21

Similar to claim 18 above, Section VII.D.5, Pintauro fails to suggest the claimed vascular prosthesis. Also similar to claims 1 and 18, presented above Sections VII.D.1 and 5, Pintauro fails to disclose a first enlargement with a first and second diameter portion, recited by claim 21. Pintauro further fails to disclose the claimed second enlargement positioned at a proximal end of the tube as recited by independent claim 21. The Examiner asserts that second enlargement may be viewed as anchor 116 with valve 124 defining a lesser third diameter portion. Appellant respectfully disagrees as the asserted second and third diameter portions, as shown in FIG. 13, means that the asserted first diameter portion is no longer along a majority of the length of the tube as claimed. Instead, as shown below by annotated FIG. 13, the asserted first diameter portion is actually along an extent less than the second diameter portion, and possibly the third diameter portion. Moreover, the asserted second enlargement is not positioned at a proximal *end* of the tube, as claimed, but is instead positioned along an intermediate portion of the tube away from the end. Accordingly, Pintauro fails to anticipate the recitations of claim 21.



8. Claim 27

For similar reasons as expressed above, the anchor 14, 114 of Pintauro does not show a second portion with a variable *inner* dimension, or a second portion defining a non-circular *opening*, or an opening defining a cross-sectional *area*, as recited by independent claim 27. Specifically: 1) without a bounded region, there cannot be an inner dimension, 2) without a bounded region, an opening cannot be defined, and 3) without a bounded region (or an opening), a cross-sectional area cannot be defined (area being generally defined as a quantity expressing the two-dimensional size of a defined part of a surface, typically a region bounded by a closed curve). Accordingly, Pintauro fails to show or describe the features of independent claim 27.

E. Claims 6, 15, 17, 20, and 22 Rejected under 35 U.S.C. 103 over Pintauro

1. Claim 6

Pintauro does not provide for the claimed size. The recitations relied on by the Examiner describe circumferentially extending the anchor 14 (col. 4:17-20), integrating spring wires by adjusting wall thickness (col. 4:32-34); altering wall thickness to facilitate kinking (col. 8:3-6); and optional materials including rubbers and polyurethane (col. 8:38-44); none of which provide support for altering the device diameter dimensions. Pintauro does provide for varying the dimensions and configuration based on anatomical considerations, such as the length of the tubular body and

diameter of the tubular portion and second anchor to fit securely within the urethra. (Pintauro, col. 8:49-64.) However, there is no support for the claimed dimensions of 14-36 mm for a first diameter of the enlarged chamber and a second diameter no greater than 14 mm. The rationale to vary the Pintauro dimensions based on the diversity of pertinent anatomical dimensions found in the animal kingdom does not support a *prima facie* case of obviousness. Nowhere does the Examiner provide dimensions of any species of the animal kingdom that would result in the desired dimensions of the anchor section within the claimed range and still function as intended for controlling urinary continence (i.e. that the anchor area is sufficient to support the anchor non-surgically within the bladder). (Pintauro, col. 1:44-63.) Accordingly, the rejection of claim 6 over Pintauro is not *prima facie* supported.

2. Claims 15, 17, 20, and 22

Pintauro does not suggest the claimed polytetrafluoroethylene material, instead utilizing a silicone rubber, latex rubber, or polyurethane. (Pintauro, col. 8:38-44.) The Examiner suggests that "PTFE would have been immediately obvious from column 8, lines 45-48." (Office Action, p. 4.) However, as polytetrafluoroethylene is not listed by Pintauro as an optional material, it is unclear how the use of PTFE would have been immediately obvious. Such a conclusory assertion of obviousness without a rational articulation as to why a person of skill in the art would have made the claimed material substitution, does not support a *prima facie* case of obviousness.

F. Conclusion

Appellant respectfully submits that the Office has not established a *prima facie* case of anticipation/obviousness with respect to claims 1-11, 14-22, and 27 for at least the reasons set forth herein. Accordingly, claims 1-11, 14-22, and 27 subject to this appeal are patentable over the cited art. Favorable action is solicited and a finding of patentability of these claims is respectfully requested.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by Applicant on July 6, 2010; January 15, 2009; October 31, 2007; August 16, 2007; January 29, 2007; May 17, 2006; August 25, 2005; and January 6, 2005.

Dated: May 13, 2011

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/603,952

1. (Previously presented) A vascular prosthesis, comprising a generally tubular portion and an end formation configured for surgical connection to an opening formed in a blood vessel, said tubular portion including a generally uniform surface and a first diameter that tapers to a smaller second diameter adjacent said end formation, said end formation defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening, the opening having a non-circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the tubular portion at the first diameter.

2. (Previously presented) The vascular prosthesis according to claim 1, wherein said enlarged chamber comprises a first diameter parallel to an axis of the tubular portion and a second diameter transverse to the axis of the tubular portion, wherein said enlarged chamber first diameter is longer than said enlarged chamber second diameter, said enlarged chamber first diameter corresponding to a heel and a toe of the end formation, wherein a transition between said tubular portion and said toe is outwardly initially convex before a final concave portion.

3. (Original) The vascular prosthesis according to claim 1, wherein said enlarged chamber is configured to promote localized movement of blood having a non-laminar nature with a shear stress inducing relationship to a wall of said blood vessel.

4. (Previously presented) The vascular prosthesis according to claim 2, wherein a transition between said tubular portion and said heel is generally outwardly concave.

5. (Previously presented) The vascular prosthesis according to claim 2, wherein portions of the end formation corresponding to opposing ends of said enlarged chamber second diameter are generally outwardly convex.

6. (Previously presented) The vascular prosthesis according to claim 2, wherein said enlarged chamber first diameter is between approximately 14 and 36 mm and said enlarged chamber second diameter is no greater than approximately 14 mm.

7. (Previously presented) The vascular prosthesis according to claim 1, further comprising a second end formation.

8. (Previously presented) The vascular prosthesis according to claim 7, wherein said second end formation comprises a second enlarged chamber comprising a first diameter parallel to an axis of the tubular portion and a second diameter transverse to the axis of the tubular portion, wherein said second enlarged chamber first diameter is longer than said second enlarged chamber second diameter, said second enlarged chamber first diameter corresponding to a heel and toe of the second end formation, wherein a transition between said tubular portion and said toe is outwardly initially convex before a final concave portion.

9. (Previously presented) The vascular prosthesis according to claim 8, wherein a transition between said tubular portion and said heel of said second enlarged chamber is generally outwardly concave.

10. (Previously presented) The vascular prosthesis according to claim 8, wherein portions of the end formation corresponding to opposing ends of said second diameter of said second enlarged chamber are generally outwardly convex.

11. (Previously presented) The vascular prosthesis according to claim 8, further comprising a decreased diameter portion adjacent said second end formation.

12-13. (Canceled).

14. (Previously presented) The vascular prosthesis according to claim 1, wherein the tubular portion and end formation are comprised of a material other than autologous vascular tissue.

15. (Previously presented) The vascular prosthesis according to claim 1, wherein the tubular portion and end formation are comprised of a polytetrafluoroethylene material.

16. (Previously presented) The vascular prosthesis according to claim 7, wherein the tubular portion, end formation and second end formation are comprised of a material other than autologous vascular tissue.

17. (Previously presented) The vascular prosthesis according to claim 7, wherein the tubular portion, end formation and second end formation are comprised of a polytetrafluoroethylene material.

18. (Previously presented) A vascular prosthesis, comprising a tube and an enlargement positioned at a distal end of the tube, the tube comprising a first diameter portion extending along a majority of the length of the tube and a second diameter portion positioned adjacent the enlargement, the first diameter portion having a diameter greater than a diameter of the second diameter portion, the enlargement defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening, the opening having a non-circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion.

19. (Previously presented) The vascular prosthesis according to claim 18, wherein the open end perimeter has a generally oval shape.

20. (Previously presented) The vascular prosthesis according to claim 18, wherein the tube and enlargement are comprised of a polytetrafluoroethylene material.

21. (Previously presented) A vascular prosthesis, comprising a tube, a first enlargement positioned at a distal end of the tube and a second enlargement positioned at a proximal end of the tube, the tube comprising a first diameter portion extending along a majority of the length of the tube, a second diameter portion with a diameter less than a diameter of the first diameter portion positioned adjacent the first enlargement and a third diameter portion with a diameter less than a diameter of the first diameter portion positioned adjacent the second enlargement, at least one of the first and second enlargements defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening, the opening having a non-circular perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion.

22. (Previously presented) The vascular prosthesis according to claim 21, wherein the tube, first enlargement and second enlargement are comprised of a polytetrafluoroethylene material.

23-26. (Canceled).

27. (Previously presented) A vascular prosthesis, comprising: a tube defining a central axis, the tube having a first portion with a constant inner dimension along a first portion of the central axis and a second portion with a variable inner dimension along a second portion of the central axis, the second portion defining a non-circular opening at an end of the tube, the non-circular opening defining a cross-sectional area that is larger than a cross-sectional area of the first portion of the tube.

28-32. (Canceled).

APPENDIX B

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

APPENDIX C

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.